

QUALITY MANAGEMENT PLAN
FOR THE
ENVIRONMENTAL HEALTH SECTION

Revision 6

August 2008



**Environmental Health Section
North Dakota Department of Health
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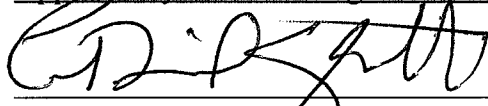
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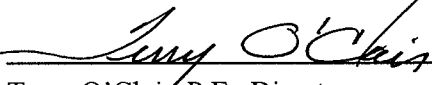
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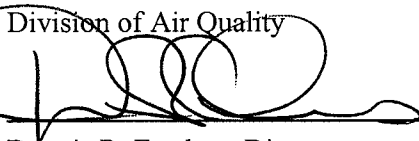
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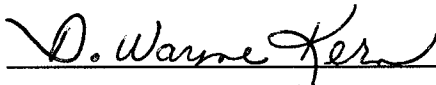
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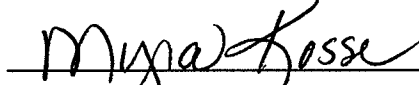
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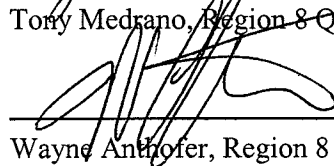
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ACRONYMS

AQ	Division of Air Quality
CBI	Confidential Business Information
CLP	Contract Laboratory Program
CO	Chief's Office
CQAP	Construction Quality Assurance Plan
DPM	Designated Project Manager
DQO	Data Quality Objective
EHS	Environmental Health Section
EPA	U.S. Environmental Protection Agency
GIS	Geographical Information System
ITD	Information Technology Department
LAN	Local Area Network
LS	Division of Laboratory Services
MF	Division of Municipal Facilities
NDCC	North Dakota Century Code
NDDoH	North Dakota Department of Health
QA	Quality Assurance
QAC	Quality Assurance Coordinator
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
QO	Quality Objective
QS	Quality System
QSR	Quality System Review
SAP	Sampling and Analysis Plan
SOP	Standard Operating Procedures
WM	Division of Waste Management
WQ	Division of Water Quality

EXECUTIVE SUMMARY

One goal of the North Dakota Department of Health (NDDoH), Environmental Health Section (EHS), is to ensure that all environmental projects produce data results that are of known quality and that the data results are of the quality needed and expected for their intended uses. Because environmental data of the EHS are frequently used in environmental decisions, that data must be of sufficient quality, adequate quantity, appropriately documented and scientifically and legally defensible.

Specific quality management processes are used by EHS personnel during all data collection and data interpretation activities performed during conduct of EHS business. The specific quality management practices used in the EHS make up the Quality System (QS) as described in this Quality Management Plan (QMP). This QMP reflects provisions of EPA Requirements for Quality Management Plans, EPA QA/R-2, and the EPA Region 8 Quality Management Plan. It applies to all EHS activities that generate or obtain data that characterize or assess environmental media, effluents, and wastes. These activities are categorically listed as follows:

1. Data generated by the sampling of air, water, land and wastes and the laboratory analyses of the samples,
2. Data generated and used for design, construction and operation of remediation or treatment systems,
3. Data generated through computer modeling efforts, and
4. Data acquired from sources outside the EHS, for example, from EPA and through databases, publications and contracts for services.

The EHS organization and management principles, as identified in this document, rely on staff empowerment and encouragement of good performance to attain the goals and objectives of this QMP.

QUALITY MANAGEMENT PLAN

ENVIRONMENTAL HEALTH SECTION

1.0 ORGANIZATION AND MANAGEMENT

1.1 Document Purpose

This Quality Management Plan (QMP) describes the quality management processes of the North Dakota Department of Health (NDDoH), Environmental Health Section (EHS), that are used to maintain a Quality System (QS). Its purpose is to provide a management strategy that assures that environmental data developed by the EHS are of sufficient quality, adequate quantity, appropriately documented and scientifically and legally defensible.

1.2 Supersession

This document replaces Revision 5 of the Quality Management Plan for the Environmental Health Section, which was dated June 2000.

1.3 Statement of EHS Quality Assurance Policy

1.3.1 Definition of QA and QC

Quality Assurance (QA) is an integrated system of management activities involving planning, implementation, assessment, reporting and quality improvement to ensure that a process, item, data or service is of the type and quality needed and expected by the decision makers and the public.

QA is implemented through the following:

1. Delineated responsibilities for QA;
2. QA Project Plans (QAPPs); and
3. QA training.

Quality Control (QC) is the overall system of technical activities that measures the attributes and performance of a process, item or service against defined standards to verify that the process, etc., meets the stated QA objectives and/or requirements. QC is typically implemented on a project by project basis through the review of the implementation of QAPPs and related data assessments.

1.3.2 Importance of QA and QC

The EHS goals regarding environmental contaminants are:

1. To identify the presence of environmental contaminants in areas of potential exposure to humans and the environment;
2. To determine impacts of environmental contaminants on human health and ecosystems;
3. To determine whether, how and by whom such threats to human health and the environment should be remediated; and
4. To monitor compliance with environmental regulations.

QA and QC are integral to the functions of the EHS because quality data ensures the scientific credibility of the information upon which decisions are based. Proper QA enhances proper planning, reducing the likelihood of duplicate or repetitive sampling, thereby reducing costs to the public.

1.3.3 Objectives of QA and QC

Environmental data collected by the EHS are generally intended for input to a decision process. It is imperative that EHS decisions be supported by environmental data of sufficient quality and adequate quantity that are appropriately documented and scientifically and legally defensible.

The EHS QS is designed to encourage, monitor and assure that environmental activities are both well planned and designed to address the needs and objectives of the EHS projects conducted in North Dakota. The primary objective of the EHS QS is to ensure that all environmental projects produce data that are of known quality and of the type, quantity and quality needed for their intended use.

The objectives of the EHS QMP are to:

1. Encourage the use of QA and QC principles in the management of environmental projects;
2. Facilitate the timely identification, improvement and/or correction of problems and QA systemic weaknesses;
3. Identify EHS staff training needs; and
4. Provide for continuous improvement in project operations.

The primary management principles that the EHS uses in its QS are:

1. Empowerment of staff; and
2. Promoting good performance as opposed to the use of punitive management practices.

1.4 Organization and Responsibilities

1.4.1 EHS Organization and Data Generation

The EHS is one of seven sections of the NDDoH. Each section is sub-organized into divisions. The EHS is organized as follows:

Chief's Office (CO)

Division of Air Quality (AQ)

Division of Laboratory Services (LS)

Division of Municipal Facilities (MF)

Division of Waste Management (WM)

Division of Water Quality (WQ)

Each division in the EHS is headed by a director who reports to the EHS Chief, as illustrated in the EHS organization chart (Figure 1). Within the AQ, MF, WM and WQ divisions, staff are organized in programs (Figure 1). Those programs that have projects¹ which generate environmental data are responsible for QAPPs² developed in accordance with the requirements presented in this QMP.

The EHS may, on occasion, contract for environmental services in fulfillment of duties delegated by state law. In such circumstances, the requirements presented in this QMP also apply to those acquired contractual services (See Sections 1.4.3, 1.5 and 3.5).

The CO is responsible for oversight of the EHS's QS for QA and QC as described in this QMP, while each program is responsible for the preparation, implementation and assessment of its QAPP(s).

1.4.2 Position and Authority of QA Officer

The EHS Quality Assurance Coordinator (QAC) is located in the CO. The QAC normally operates independently of direct environmental data generation, model development and technology development. The QAC reports directly to the Chief of the EHS.

¹ A distinction is made between program and project throughout this QMP, since "program" refers to an organization unit. Programs are shown in Figure 1. A program can be responsible for more than one project. When a program conducts only one project, the terms program and project are interchangeable.

² Any reference to a QAPP in this QMP shall be construed to be synonymous with Sampling and Analysis Plan (SAP).

This reporting relationship provides the QAC with sufficient authority to assure independent oversight of the implementation of the QS throughout the EHS.

The minimum qualifications of the QAC position are a Bachelor's degree in physical, environmental, chemical or biological sciences or engineering and five years experience in the environmental health field, two years of which involves environmental field testing or laboratory analyses and /or equivalent combinations of education and experience which indicates a thorough knowledge of EHS requirements, testing procedures, QA and QC, and supervision.

1.4.3 Management and Staff Responsibility for QA

It is the policy of the EHS that the primary responsibility for QA resides with each program manager and/or Designated Project Manager (DPM) and each program staff member in each division. QC, the oversight and improvement of QA implementation and performance which is an integral part of program management and contractor oversight, is vested with DPMs, program managers and division directors.

In the case of grants, cooperative agreements and similar instruments in which the EHS awards money to a second party for the performance of environmental work, the DPM who has oversight shares responsibility for implementation of a QS with the award official for the said instrument. Specific responsibilities are elaborated upon in Section 1.6 of this QMP.

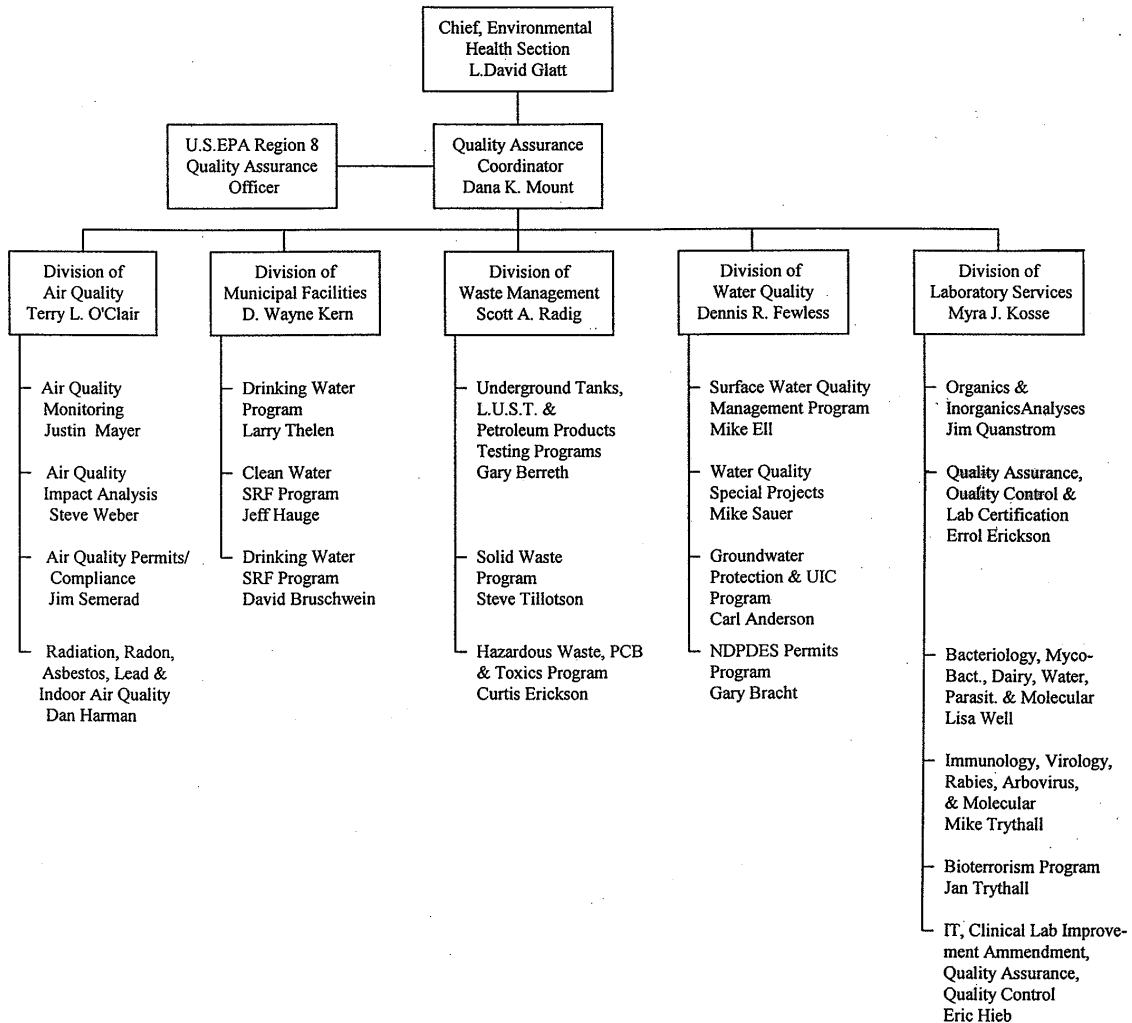
Program managers report to the director of the division in which they are located, and generally provide leadership and supervision to staff, some of whom serve as project managers. Program managers are responsible for identifying environmental projects for which QA and QC are needed.

The DPM is the staff member who works within a specific project and has immediate managerial or technical control of that project (See the program managers that are shown in Figure 1). The DPM is responsible for specifying the quality of the data required for each project and for approving the QAPP. The DPM may also be a program manager.

For the purposes of this document, the DPM is the person with responsibility and authority to approve a QAPP. In cases where the identity of the DPM is not clear or responsibility may rest in more than one individual, program management will designate a single individual to perform that function for the designated project.

1.4.4 Resources

Program managers, together with DPMs, must determine the resources needed to assure that an adequate level of QA and QC is achieved for all projects within their respective programs. Division directors must assure adequate resources in their management and budgeting strategies.



Environmental Health Section Organization Chart

Figure 1

1.5 Types of Activities Specifically Covered by QMP

This QMP applies to all EHS activities that generate or obtain data that characterize or assess environmental media, effluents and wastes. These activities are categorically listed as follows:

1. Data generated by the field sampling of air, water, land and wastes and the laboratory analyses of the samples;
2. Data generated and used for design, construction and operation of remediation or treatment systems;
3. Data generated through computer modeling efforts; and
4. Data acquired from sources outside the EHS, for example, from EPA and through databases, publications and contracts for services.

Certain data collection activities are not covered by this QMP; these activities are listed in Section 1.5.5 of this QMP.

Whenever these activities are performed by EHS personnel or EHS contractors, the DPM has full responsibility for ensuring that all EHS QA and QC requirements are met. When such activities are performed with EHS funds, the DPM having oversight is responsible for ensuring that the receiving organization complies with all relevant EHS QA and QC requirements.

Activities performed by members of the regulated community that do not use EHS funds are not covered under this document. In the absence of regulatory requirements that would take precedence, DPMs are encouraged to include EHS QA and QC requirements as part of any negotiated agreement with the regulated party.

Chapter 2.0 of this document identifies the specific EHS QS applicable to each of the identified categories. The environmental activities included in each category are discussed in the following sections.

1.5.1 Data Generated by Field Sampling and Laboratory Analysis

Some examples of covered activities are the generation of environmental data, including field work for the purposes of collecting samples for later chemical, physical or biological analyses; the collection of in situ measurements; field work for site reconnaissance; and compliance inspections.

Environmental media samples for chemical, physical or biological analyses are commonly collected and analyzed to accomplish the following goals: 1) confirm the presence or absence of pollutants or contaminants; 2) determine concentration levels of various sample components; 3) delineate the horizontal and vertical distribution; 4) evaluate rate and direction of transport; 5) determine eventual fate of the identified pollutants; 6) determine the baseline and background concentrations; 7) determine the effectiveness of treatment; 8) determine their sources of contamination; 9) establish time trends; 10) monitor change; 11) evaluate progress; and 12)

evaluate compliance with environmental laws and regulations. Sampling activities may be conducted for site characterization, for ongoing monitoring projects, or during remediation and removal activities.

Data may also be collected to use as an input for risk screening and/or assessment calculations incorporating exposure to humans, wildlife and the environment. Such risk calculations may be used in any EHS program as appropriate or required by regulation or EHS policy. Data collection activities conducted for the EHS must be adequately addressed in a QAPP, which includes data quality objectives (DQOs). The required elements for QAPPs are discussed in Section 3.1 of this document, and suggested additional elements are listed in Chapter 8.0.

Activities covered under this category include collecting media samples in the field, observing and recording field observations, performing analyses in the field and in-field laboratories, and analyzing samples in laboratory settings. Examples of media include solid or liquid waste, fluid discharges or emissions, groundwater, surface water, soil, sediment, air, and biota. Measurements include physical measurements and observations made in the field such as flow rates, water levels, particle sizes, geological matrices, temperature, wind speed and direction. Biological monitoring and sampling activities such as habitat evaluation, species identification and diversity assessments are also covered under this category. Portable equipment is used to make field chemical determinations of parameters such as pH, specific conductance and dissolved oxygen. Analyses of chemical constituents can take place in field laboratories or at commercial or government laboratories. The QAPPs must describe methods of collection, methods of analyses, methods of transportation and methods of documentation for each of these activities.

1.5.2 Design, Construction and Operation of Remediation or Treatment Systems

The design, construction and operation of environmental technology must be supported by an effective level of QA and QC to assure that performance of the technology meets expectations. Environmental technologies include bench scale and pilot treatment projects to determine effectiveness, and the design, construction and monitoring of remediation systems. Environmental technologies may include emission/effluent control, waste remediation, and pollution abatement, and may utilize mechanical, chemical or biological processes.

The QS for control of construction activities is discussed in Section 3.5 of this document.

1.5.3 Data Generated Through Computer Modeling

EHS decision makers sometimes use data generated from computer models of environmental behavior that have been developed by both the EHS and outside sources. The QS used by the EHS for control of model generated data is discussed in Section 3.4.1 of this QMP.

1.5.4 Data Collected from Outside Sources and Databases

EHS decision makers sometimes use information and data from outside sources or databases. Examples of such data include, but are not limited to, toxicological data, historic stream

characteristic and flow data, climatological data, field data collected by a regulated party and exposure data.

When data from outside sources are used, EHS staff are encouraged, whenever possible, to obtain and review the QA and QC practices that were followed during the original data generation. Professional judgement must be used to weigh the value of all information and data used in EHS decision making. It is not feasible for EHS staff to thoroughly review and validate all information and data obtained from outside sources. The quality system used in the EHS for outside data is discussed in Section 3.4.3 of this QMP.

In addition, any data that is used for purposes other than that originally intended must also be reviewed to ensure that the data are suitable for the new application.

1.5.5 Activities Not Covered

The environmental sampling or data collection activities that are not covered by this QMP are:

1. Data collected only for safety or workplace regulations; and
2. Collection of employee medical monitoring data.

1.6 Policy on Cooperative Projects and Sites

The EHS, on occasion, uses external entities for the collection and analyses of environmental samples and data that are later used for decision making. The activities of these entities are managed through grants, cooperative agreements, interagency agreements, or contracts.

Examples of entities external to the NDDoH and the EHS include, but are not limited to, potentially responsible parties, state and local agencies, and EHS contractors. Oversight may be conducted through periodic reviews by EHS staff of the entities' activities.

Specific requirements for environmental sampling or data collected by outside entities that receive EHS funding are described in the numbered items that follow:

1. Agreements and contracts with state agencies, universities and academic institutions, tribes and communities shall require that QAPPs and/or SOPs for any environmental sampling be prepared. The DPM, who has the oversight, is responsible for review and approval of QAPPs and/or SOPs;
2. If work by a private party is required under an enforcement agreement, the enforcement agreement will detail the QA and QC roles of the EHS and the party; and
3. If work by a private party is voluntary (no formal or enforcement agreement) and will be provided to the EHS for acceptance, EHS review and approval of the work's QA is suggested in order to avoid misunderstandings of the work's goals and data usage. The private party has the right to proceed without such approval,

but the EHS can decide not to use the data, if the data are judged as not adequate to support the data's proposed use.

1.7 Document Distribution

This QMP will be distributed by email to everyone listed in the EHS organizational chart (Figure 1). In addition, this QMP will be posted on the NDDoH's website which is accessible by EHS staff and the public.

2.0 QUALITY SYSTEM AND DESCRIPTION

2.1 General Quality System

The EHS Quality System (QS) is coordinated by the CO and described in this QMP.

This QMP reflects relevant provisions of EPA Requirements for Quality Management Plans, EPA QA/R-2, EPA/240/B-01/002, March 2001 (Reissued May 2006); and related provisions of the Quality Management Plan for the U.S. Environmental Protection Agency Region 8, November 2002.

The QAC is responsible for maintaining and updating the QMP. This QMP will be reviewed annually by the EHS and its QAC and adjusted, if appropriate, in content and applicability.

Division Directors are responsible for assuring that staff understand the QS as described in this QMP. All project QAPPs must be consistent with the EHS's standard for such plans as described in Chapter 3.0.

2.2 Team Approach

Each DPM has access to technical experts for assistance in quality objectives development, evaluation of project work plans and associated QA documents. Within the EHS, there are groundwater sampling specialists, hydrologists, geologists, chemists, scientists, engineers, waste management specialists, biologists, microbiologists, air quality modelers, water quality modelers and air quality specialists. Each project team leader or DPM should involve the appropriate specialists relevant to site or project issues. The DPM has the primary responsibility to ensure the environmental data collected are of the type and quality required to meet the objectives of the project.

2.3. Scope of Application

The EHS QS applies to all EHS projects during which environmental samples are taken for the purpose of performing chemical, physical or biological tests and generating environmental data. It applies to activities that are conducted directly by EHS personnel, activities performed under EHS contracts, agreements or grants, when resulting environmental data are intended for use in EHS funded projects. QA requirements for data acquired from other sources are covered under Section 3.4.3 of this QMP.

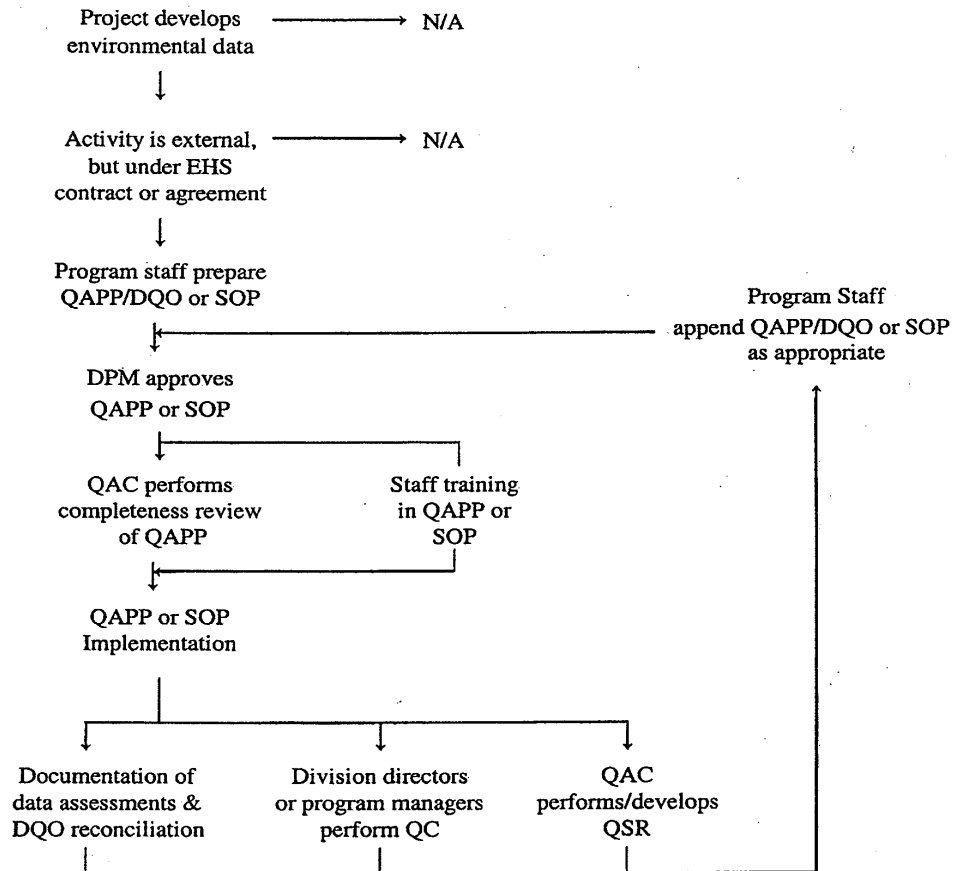
The QS is also intended to be used as a model in all negotiated agreements, consent decrees etc., in which the EHS directs or requests that another party, such as another state agency or regulated entity, perform data collection activities for use in EHS programs.

2.4 Components of the Quality System

The QS for the EHS consists of the following components:

Quality Assurance Project Plans	Chapter 3.0
Personnel Qualifications and Training	Chapter 4.0
Procurement of Items and Services	Chapter 5.0
Records	Chapter 6.0
Computer Hardware and Software	Chapter 7.0
Planning	Chapter 8.0
Work Processes	Chapter 9.0
Quality Assessment and Improvement	Chapter 10.0

A paradigm of core QS provisions in this QMP is shown in Figure 2.



Abridged Paradigm for the EHS Quality System

Figure 2

3.0 QUALITY ASSURANCE PROJECT PLANS

3.1 QAPPS

Each division or program is responsible for developing Quality Assurance Project Plans (QAPPs) for its projects, and all QAPPs must be consistent with the QMP.

DPMs are responsible for approval of QAPPs and periodic review of the implementation of QAPPs, including SOPs (See Chapters 9.0 and 10.0). The QAC is responsible for reviewing the completeness of QAPPs.

QAPPs must be developed as specified in EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5, EPA/240/B-01/003, March 2001 (Reissued May 2006).

All environmental data collection activities conducted by or on behalf of the EHS must be addressed in a QAPP. The following 24 elements must be adequately addressed in a QAPP:

Project Management

- A1 Title & Approval Sheet
- A2 Table of Contents
- A3 Distribution List
- A4 Project/Task Organization
- A5 Problem Definition/Background
- A6 Project/Task Description
- A7 Data Quality Objectives (DQO) and Criteria
- A8 Special Training/Certification
- A9 Documents and Records

Measurement/Data Acquisition

- B1 Sampling Process Design (Experimental Design)
- B2 Sampling Methods
- B3 Sample Handling & Custody
- B4 Analytical Methods

- B5 Quality Control
- B6 Instrument/Equipment Testing, Inspection, and Maintenance
- B7 Instrument/Equipment Calibration & Frequency
- B8 Inspection/Acceptance of Supplies and Equipment
- B9 Non-direct Measurements (Secondary Data)
- B10 Data Management

Assessment/Oversight

- C1 Assessments and Response Actions
- C2 Reports to Management

Data Validation and Usability

- D1 Data Review, Verification, and Validation
- D2 Verification and Validation Methods
- D3 Reconciliation with Data Quality Objectives and User Requirements

Because the level or degree of QA/QC activities needed for each project differs, the EHS believes the graded approach should be employed in planning the work. As such, one or more of the 24 elements may not apply to a particular project (N/A), or it may be more appropriate to combine one or more elements into a single item. In that case, a reference to the combined item should be made when discussing a particular QAPP element.

QAPPs must be reviewed for technical adequacy and compliance with the QMP and approved by an appropriate EHS representative prior to scheduling sampling or laboratory services. This approval is performed jointly by the QAC and a DPM. Although DPMs are free to use any variety of technical resources to assist in the review, in no case shall approval be delegated to anyone outside of the EHS. QAPPs for long term projects must be reviewed at least every year for continued relevancy and revised as needed, although a QAPP may be revised at anytime the DPM deems necessary. Revisions to a previously approved QAPP must undergo the same review and approval process as the original version.

Every field investigation must be conducted in accordance with an approved QAPP to ensure that DQOs will be met. When splits are collected for oversight purposes from the regulated community, the approved project QAPPs already in place are used to define the EHS's sample handling and analytical requirements. In this case, the EHS does not prepare additional QA documents to define the sample collection and handling activities.

3.2 Control of Data Collection Activities

Certain practices are required to control environmental data collection activities. These practices are described in the sections below and include the following:

1. Development and approval of a QAPP;
2. Development of DQOs;
3. Production of a report documenting reconciliation with DQOs; and
4. Satisfaction of minimum analytical QA and deliverable requirements.

3.2.1 Approved QAPP

The preparation, review and approval of a QAPP as described in Section 3.1 is required practice for all environmental data collection activities in the EHS. Certain emergency actions are permitted under a pre-existing generic QAPP. These actions are limited to time critical events and true emergencies which pose an imminent health or environmental threat requiring immediate actions by EHS staff or contractors.

3.2.2 Data Quality Objectives

The development of DQOs are required. For many projects, DQOs may be a simple statement of why data are being collected and what data outputs will be considered significant. QAPP reviewers must assure that the QAPP specifically addresses the technical adequacy of DQOs.

For some projects it may be appropriate to use the complete statistical hypothesis testing approach as described in Guidance on Systematic Planning using the Data Quality Objectives Process, EPA QA/G-4, EPA/240/B-06/001, February 2006.

DQOs are intended to accomplish the following:

1. Clarify the study objectives;
2. Define the most appropriate types of environmental samples or data to collect;
3. Determine the most appropriate conditions for collecting the environmental samples or data; and
4. Specify the level of uncertainty that is acceptable as the basis for establishing the quantity and quality of the data needed (i.e., sufficient quantity and adequate quality).

3.2.3 Documentation of DQOs Reconciliation

Elements D1, D2 and D3 of Section 3.1 require that QAPPs identify data assessment procedures. These elements specifically include items on how data will be reviewed, validated and qualified. Element D3 requires reconciliation with stated DQOs and user requirements. An assessment of the usability and limitations of the field and analytical data collected, with respect to the original DQOs, must be documented after completion of all data collection activities.

3.2.4 Minimum Analytical QA and Deliverable Requirements

All analytical work performed must be as specified in a project QAPP, and must meet minimum standards as defined in the laboratory's Standard Operating Procedures (SOPs) and the specific method employed. Any additional QA/QC and deliverable requirements that are contained in the technical specifications in a project QAPP must also be performed, documented and provided by the laboratory. Failure to comply with these requirements may result in rejection of data, and, where applicable, nonpayment for the defective products.

3.3 Standard Operating Procedures

EHS staff are encouraged to incorporate the use of a SOP whenever a task is to be repeated frequently. The use of SOPs promotes reproducible work products and consistency in and among EHS project operations. An SOP may be prepared by any staff member whenever such SOP is desirable. SOPs are then approved by the program manager (See Section 1.4.3). QAPPs may include SOPs.

3.4 Quality System for Data Collected from Modeling, Electronic and Database Sources

3.4.1 Computer Modeling Data

EHS staff frequently make use of mathematical and computer based environmental models for the prediction of certain environmental events and effects. The reliability of the outputs of such modeling efforts are dependent upon the accuracy of the input data, on the suitability of the model, and on the accuracy of the modeling process. It is not feasible for EHS staff to verify, calibrate and/or validate all models which may be used; however, EHS staff are encouraged to use well known or established models whenever those are available.

When computer models are used to predict events or effects, certain documentation of the input data and the model used is required. Within the project documentation, the DPM must indicate the name, source, and identification information for the model used, including version number if appropriate. In addition, the DPM must identify the source for any input information used within the model. The DPM must indicate whether the data used as model input were collected by the EHS under the other applicable provisions of this document, or whether the data were obtained from a "secondary" source such as an agency, industry, a database or a publication. If a secondary source was used and more than one source of appropriate secondary data was available, the DPM must explain why that particular source was selected.

A description of the computer hardware and software that are used by the EHS is contained in Chapter 7.0.

3.4.2 Environmental Database Systems

All environmental database system administrators will need to identify any major data quality weaknesses of their data system and establish a timetable and plan for improvement. This will require the development of written QA/QC plans for all EHS database systems. Protocols dealing with data ownership, data accuracy, timeliness, and completeness of data will be promoted in a model guide. This will define the data quality for the system and how it is measured, and include what practices and tools will be used to ensure that these quality standards are met consistently. The programs use their respective database systems for environmental decision making. Through inspections, split sample analysis, and performance audits the programs are responsible for verifying the accuracy and validity of the data, and for follow-up on questionable data. Section 7.3 contains additional discussion of this topic.

3.4.3 Data Obtained from Outside Sources

EHS staff occasionally use data and information collected or generated by sources outside of the EHS. These sources are frequently referred to as “secondary” data sources. There are numerous possible secondary data sources. Examples of these include, but are not limited to, toxicological data used in risk assessments, climatological data, historic stream flow and monitoring data collected by other federal and state agencies, new technological and scientific issues covered in the scientific literature and data collected by other parties without the use of EHS funds.

When using secondary data, it is usually not possible for the EHS to validate or review all of the data. In this situation, the EHS requires that the DPM assure that project files and records indicate the source of the data and any efforts that may have been taken to review or validate the data. If multiple sources of the same or similar information are available, the project records should indicate why the source used was chosen.

3.5 Quality System for Remediation Systems

3.5.1 Construction Quality Assurance Plan

The EHS requires the preparation of a Construction Quality Assurance Plan (CQAP) whenever EHS funds are used to design, construct or operate a remediation system. A remediation system is any system intended for storage, handling or treatment of wastes or contaminated media prior to discharge to the environment. These systems often include facilities constructed as a surface impoundment, waste pile, landfill, waste isolation system, artificial wetlands, treatment facility, or similar system. This requirement is not to be applied to actions conducted in response to a true emergency as a time-critical response.

The CQAP must be reviewed and approved by the EHS DPM with authority over the site or grant. A CQAP must address the following elements:

1. Responsibilities and Authorities of Organizations and Key Personnel Involved;

2. Personnel Qualifications;
3. Inspection Activities;
4. Sampling Strategies and Corrective Actions; and
5. Documentation.

Although the preparation of a CQAP is not required of regulated entities that do not receive EHS funds, it is strongly advised that this item be included as part of negotiated agreements as appropriate. An explanation of each component of the CQAP is provided in the following sections.

3.5.2 Responsibilities and Authorities

All organizations involved in the design, construction and operation of the system shall be identified. To the extent known, key personnel should also be identified. A discussion of authorities and responsibilities of the organizations, as they relate to the plan, shall be included. Responsibilities of key personnel such as the Construction QA Manager and the DPM shall also be included.

3.5.3 Personnel Qualifications

Qualifications of key project personnel such as the Construction QA Manager and the construction inspector will be presented in the CQAP.

3.5.4 Inspection Activities

The CQAP shall present the observations, tests and inspections which will be used to assure that the installation meets or exceeds all design criteria, plans and specifications. Schedules or periodic frequencies for these activities shall also be established. Any system which is designed to treat or remediate waste material or a waste stream must also include tests to measure the efficiency of the waste treatment/reduction process or show that effluents are in compliance with appropriate state or federal regulations.

Typically inspection activities will be visual observations, field testing and measurements, laboratory testing and evaluation of test data. Most often these will be associated with one of the following four items:

1. Inspection of materials used to certify that they meet design criteria;
2. Construction Quality Control to measure conformance with project plans, specifications and design criteria;
3. Construction Quality Assurance to determine final product quality and conformance with project specifications. For larger projects, it is recommended that periodic inspections be conducted at the completion of various phases rather than waiting until final completion; and

4. Regulatory Inspections performed to ensure compliance with all applicable codes, regulations and permits.

3.5.5 Sampling Strategies and Corrective Actions

The CQAP must address sampling methods, sample size, methods for determining sampling locations, frequencies of sampling, test methods, and acceptance and rejection criteria for compliance with design specifications. The corrective actions to be taken due to failed tests must be addressed in the CQAP.

3.5.6 Documentation

This portion of the CQAP will describe what QA reports are to be made during various phases of design and construction and also those produced while the system is in operation. It shall include a discussion of the content of the report, the frequencies of the reports, responsibility for production of the reports and to whom the reports are to be directed.

4.0 PERSONNEL QUALIFICATIONS AND TRAINING

4.1 Qualifications

The North Dakota Department of Health (NDDoH) participates in the state employee classification system administered by the state's Office of Management and Budget, Division of Human Resource Management Services. All job positions of the EHS are classified, and each class has a written description of general duties, required education or training and related applicable experience.

The EHS employs engineers, scientists, geologists, biologists, chemists, microbiologists and other specialists for job functions that relate to or include environmental testing, information analyses, media sampling, and data interpretation. The education, coupled with training and work experience, provides the EHS's technical staff with knowledge in technical disciplines that are the foundation for QAPP and/or SOP implementation.

Division directors, program managers and DPMs also possess knowledge of state laws, state rules and guidelines of assigned programs (See Figure 1).

4.2 Training

Training of EHS technical staff should occur when an employee lacks prior relevant or direct experience in the specific QAPP or SOP. The training should be given by senior EHS program or technical staff that have a minimum of two years of relevant on-the-job experience and that are proficient in the QAPP or SOP. The training can occur by demonstration in the class room, on site and/or in the laboratory or via the internet as may be appropriate.

4.3 EPA Supplemental Training

EHS staff will participate in EPA quality assurance training, when such training is scheduled by EPA in North Dakota. All EPA training will be arranged with the EHS QAC or supervisory people. In particular, the following training themes are recommended:

1. Regional QS Strategies;
2. Data Quality Objectives; and
3. QA Project Plans and SOPs.

5.0 PROCUREMENT OF ITEMS AND SERVICES

5.1 Procurement of Supplies

Common office supplies are ordered by requisition from the state's Office of Management and Budget, Division of Central Services. Some sampling supplies are purchased from retail hardware outlets and equipment suppliers.

5.2 Selection of Contractors

Contractors are chosen by open competition and are evaluated based on their abilities to provide services. QA and QC services are typically included in these contracts. Prime contractors choose their subcontractors and are responsible for oversight of the performance of these subcontractors, which often includes QA and QC functions.

5.3 Evaluation of Deliverables

Deliverables received from contractors are reviewed by the DPM to ensure the objectives of the work are met and recommendations justified and documented. Written approval by the DPM is often required by the contract. If unsatisfactory work is received that cannot be rectified through revisions or re-sampling, the contracting officer and/or project officer is notified. Contractual requirements addressing the QA and QC requirements are generally based on the project QAPP.

6.0 RECORDS

6.1 Documentation and Handling

It is EHS policy to adequately document its organization, functions, policies, decisions, procedures, and transactions. This policy is guided by the records archival policies of the state's Information Technology Department, Records Management Division, and any applicable record retention requirements of delegated federal EPA environmental laws.

All documents in ND are subject to the state's open records law, unless declared enforcement protected by legal council. Each Director, program manager or DPM is responsible for records relevant to their Division, programs or projects.

All project records shall be kept in an official project file by the DPM. Project records shall be, as a minimum, retained in the office for the life of the project or until updated or obsolete plus a minimum of three years. They then may be disposed by landfill or transfer to state archives. Each Division, program or project shall determine its own records retention and disposal schedule for each project.

6.2 Confidential Documents

Some documents collected, received, or generated may be, by nature and content, documents which require special handling procedures. Documents of this category may be, but are not limited to, enforcement sensitive/enforcement confidential, attorney/client, or confidential business information (CBI). Each project that works with documents of this nature have specific handling procedures which are over-riding. Documents that are classified as CBI are handled as required by project specific CBI requirements. Only EHS staff are allowed to see documents classified as enforcement confidential. All confidential documents must fit one of the exceptions enumerated in the state's open records law, which is NDCC Chapter 44-04.

6.3 Document Preparation

Planning documents and project reports are prepared by EHS staff members at multiple levels. The EHS also allows contractor personnel to prepare drafts of documents, whenever that task is within the purview of the contract.

Revisions of any document that requires an approval process must also be approved in the same fashion as the original document. It is the responsibility of the DPM to maintain revision control as well as ensure that all parties using the document have the current version. Removal of obsolete and superceded documents should be accomplished in the same manner.

EHS staff are encouraged to incorporate the use of SOPs whenever a task is to be repeated frequently. The use of SOPs promotes reproducible work products and long term consistency in EHS operations. SOPs may be prepared by any staff member whenever it is felt that the existence of such SOPs is desirable. SOPs are then approved by the program manager. Transmittal and distribution of SOPs and related documents are the responsibility of the program manager and/or DPM.

6.4 Requirements for Field Documentation

Documentation of field activities establishes procedures, identifies written records, enhances and facilitates sample tracking, standardizes data entries, and identifies and establishes authenticity of the sample data collected. Proper documentation ensures that all essential and required information is consistently acquired and preserved. Timely, correct, and complete documentation establishes the chain-of-custody, a requirement for data intended for use to provide evidence for court proceedings.

Field records shall be generated and stored as specified in project specific QAPPs and SOPs.

Guidance for field records is provided in Standard Operating Procedures for Field Sampling Activities, EPA Region 8, June 1994, and its subsequent revisions.

7.0 COMPUTER HARDWARE AND SOFTWARE

7.1 Computer Hardware

The EHS has a Local Area Network (LAN). Access onto the LAN is through security password only. The state's Information Technology Department (ITD) maintains the network. The data on LAN servers are backed-up and checked daily for computer viruses by the EHS computer system administrator. Real-time virus checking is also employed. The EHS computer system administrator is located in the CO and reports directly to the Chief of the EHS.

The ITD also establishes policies and standards for purchasing network hardware and network software. Personal computers used by EHS staff are procured and maintained by the EHS divisions staff.

The DOH biennially prepares an information technology plan per a requirement of the ITD. A DOH Information Technology Committee determines whether each division is supplied with adequate and appropriate hardware and software technology.

7.2 General Computer Software

Computer software for completing basic office tasks is available through the LAN and is maintained by the EHS system administrators. This software provides word processing, database, and internal communication functions. In addition, three work stations feature access to geographical information systems (GIS) software, other specialized software and digital information for mapping. North Dakota has a GIS steering committee which includes representatives from government, education and business to guide and develop standards and policies relating to GIS hardware, software and data standards. The committee provides a forum for the sharing of ideas and solutions relating to GIS applications in the state.

7.3 Environmental Database Systems

EHS environmental data base systems are maintained either by EPA or by the EHS. Each system has its own update and backup schedule. Access is controlled by the responsible database systems administrator.

A list of software used by the EHS to supply³ EPA with data and information or to locally archive data follows.

Laboratory Services:

Chemistry:

Microbiology:

Northwest Analytical LIMS

StarLIMS version 9.0

Drinking Water:

SDWIS version 2.1

³ Information provided or encoded in accordance with existing data protocols and/or any specified federal program delegations or agreements.

Surface Water 319 Watershed Projects:	GRTS Database (direct entry)
Surface Water:	STORET version 2.0 (through 12/2008) WQX (start 01/2009)
	Sample Identification Database (SID) (Access 2003)
	Ecological Data Application System (EDAS) (Access 2003)
	Assessment Database (ADB) (Access 2003)
Water Quality:	NDPDES State Database & PCS/ICIS Database
Air Quality:	Permitting & Compliance Database
UST and LUST programs:	UST Access 2003
Hazardous Waste	RCRAInfo
Asbestos Control	ACTS version 7

Documentation, development and training are provided by the respective database systems administrators in each division/program.

7.4 Specialized Computer Models

The specific QS for control of electronic data is contained in Section 3.4 of this document.

Computer modeling is used to predict outcomes, based on the current conditions and on extrapolations or measurements of previous conditions. Modeling programs have been developed to predict migration routes and rates, and estimate contaminant distribution and concentrations for use with several fluid media, including ground water and air. Such models are prepared with site-specific parameters, and are calibrated using known data before predictions are attempted.

Briefly, a model's suitability can be ascertained based on:

1. The suitability of a model's conceptual approach;
2. The logic of a model's simplifying assumptions;
3. The presence of well defined, understandable limitations;

4. Data needs and data quality needs consistent with the project objectives;
5. EPA peer review and/or stakeholder acceptance of model output; and
6. Compliance with relevant guidance.

7.4.1 Requirements for Modeling Efforts

The EHS uses mathematical models to make systematic regulatory assessments and environmental decisions; determine environmental fate and transport; estimate pollutant loadings; develop protection zones; assess exposure, hazard, damage, and health risk; and to make projections and predictions. For these reasons the EHS must assure itself of the quality of all modeling systems. All information regarding the suitability of a model and its outputs must be documented in writing and contained in the project records. The use of SOPs is recommended for:

1. The selection of a model for use; and
2. The assessment of results for all environmental model data generated.

7.4.2 Responsibilities, Authorities and Personnel Qualifications

Individual DPMs with direct or oversight authority for any project are responsible for assuring the suitability of all models and data received by the EHS.

To the extent possible, DPMs should be familiar with the qualifications of all contractor or grantee personnel conducting modeling efforts. All personnel conducting modeling exercises must have the education and experience appropriate for the job.

8.0 PLANNING

The planning document for the generation and acquisition of environmental data is the QAPP. A complete QAPP contains several topical elements, including DQOs (See Section 3.1).

Additional topical elements that should be included in the QAPP, when appropriate, are:

1. Project customers;
2. Schedules and critical milestones;
3. Applicable laws and rules;
4. Applicable SOPs;
5. Existing information or data;
6. Documentation of the QAPP's implementation;
7. Assessment of the QAPP's functionality;
8. Distribution of the QAPP; and
9. Project budget.

9.0 WORK PROCESSES

9.1 Pre-sampling Requirements

Development and implementation of a QAPP or SOP is required for all projects that produce environmental information or data (See Section 3.2.4). An approved QAPP or SOP must be available before any samples are collected and/or analyzed. An exception to this may be a “classic emergency” and a time-critical agenda.

Once a QAPP or SOP is completed and approved for implementation, the DPM informs EHS program staff or other persons, as needed, of QAPP or SOP requirements (See Sections 1.4.3, 3.1 and 3.3). Those EHS staff or other persons that implement these requirements should be briefed and/or trained (See Section 4.2).

All laboratory analyses are performed using methodologies approved and published by EPA or others such as the ASTM. Detailed analytical method SOPs for many analytes are found in the Division of Laboratory Services methods manuals. Upon completion of analyses, the Division of Laboratory Services transmits data electronically and/or by hard copy to appropriate EHS staff.

9.2 Laboratory Coordination

Requests for environmental sampling assistance and analytical services from the Division of Laboratory Services (LS) are scheduled on a first come first served basis, unless otherwise prioritized by EHS senior management. Requests are received through the LS. The LS Director discusses projects with the laboratory staff as needed. Personnel within the laboratory may be asked to provide technical assistance in the development of QAPPs or SOPs. This up-front involvement is helpful when making arrangements for analytical services.

9.3 Documentation

Any deviation in a QAPP or SOP when obtaining samples of environmental media, holding samples or analysis of samples must be documented and explained (See Section 6.4).

10.0 QUALITY ASSESSMENT AND IMPROVEMENT

10.1 Quality System Reviews

The EHS QAC shall perform Quality System Reviews (QSRs) of EHS project QA and QC activities. A QSR can be limited to a single project. The provisions of this QMP will be reviewed for thoroughness and effectiveness during a QSR.

A QSR can be used by management to assess conformance with this QMP and to target areas needing improvement. A QSR can, when warranted, culminate in a written report.

Guidance for performing QSRs is contained in Guidance on Assessing Quality Systems, EPA QA/G-3, EPA/240/R-03/002, March 2003.

The QAC will conduct an annual overall assessment of the EHS quality system and will provide a report to the Chief of the EHS and to the EPA Region 8 Quality Assurance Office.

10.2 EHS Project QC

Division directors, program managers, DPMs or individual staff members are responsible for assessing the quality of the work done under their own auspices. There are several ways this can be done, as appropriate to the specific project and the budget. Examples include:

1. Third party observation of the work in progress for an independent assessment;
2. A field audit by qualified EHS staff;
3. A laboratory audit by qualified EHS staff;
4. Data validation of selected data sets, using EHS or contractor staff; and
5. Internal audits performed by the contractor themselves.

Any QC improvement needs will be addressed at the staff level with the DPM or program manager. Issues that cannot be resolved at this level shall be brought to the Division Director's attention and, if need be, the QAC and Chief of the EHS. Appropriate changes in plans shall be made that will result in improved quality.

10.2.1 Field Audits

Field audits consist of an on-site visit to the sampling location, observation of sampling practices, review of project records and sampling SOPs, and documentation of findings. The primary intention of such audits is to ascertain whether QAPP specified practices are being followed.

When sampling is being performed by EHS personnel or EHS contractors, the lead auditor must be an EHS employee. In these circumstances, audits may be requested through the QAC, and are performed by non-project personnel to avoid the appearance of bias. All field audits will result in the production of a written report.

10.2.2 Laboratory Audits

An audit of an external laboratory used for analyses of environmental media samples may be conducted to determine and document whether the laboratory's practices and analytical procedures are consistent with QAPP and/or SOP requirements and laboratory tasking instructions. The audit may be performed while project samples are under analysis or performed after analysis is completed. The audit will consist of an on-site visit to the laboratory, observation of its analytical practices when possible, review of its QAPP and SOPs, and documentation of findings.

10.3 Laboratory QC

10.3.1 Data Inspection

When results of laboratory analyses are received, an inspection of analytical deliverables may be performed to determine whether the work performed is consistent with laboratory tasking instructions.

Such inspection is required for work performed under the Contract Laboratory Program (CLP), but may not be required for other projects. It is recommended that authorization of payment for lab work should not be made until this inspection reveals a satisfactory performance by the laboratory.

10.3.2 EHS Laboratory QC Responsibilities

The Division of Laboratory Services Quality Assurance Plan details the specific quality control responsibilities for various positions within the division. Laboratory personnel are responsible for assuring that quality control requirements in the methodologies used are adhered to and that specific QC requests for each project are followed.

10.3.3 EHS Laboratory Certifications

The Division of Laboratory Services is audited by a team from U.S. EPA Region 8 once every three years for certification under the Safe Drinking Water Act. Analyses performed under the Clean Water Act may also be reviewed by this team. In order to maintain full certification for regulated drinking water parameters, the laboratory is required to acceptably analyze each certified drinking water parameter, at least annually, in water supply performance evaluation studies acquired from approved private providers. This requirement is identical to the requirement private laboratories must meet in order to maintain full certification status for certified drinking water parameters.

In turn, the laboratory certification officer in the Division of Laboratory Services performs audits, at least once every three years, of in-state laboratories certified for drinking water, wastewater and solid/hazardous waste testing under the North Dakota Environmental Laboratory Certification Program.